IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA

WENDY SHARP, *Plaintiff*, v. ST. JUDE MEDICAL, S.C., INC., et al., *Defendants*.	No.: 1:17-cv-03181-SCJ

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT

Stephen M. Brooks
Georgia Bar No. 085151
Lucas A. Westby
Georgia Bar No. 594008
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Telephone: (404) 322-6000
Facsimile: (404) 322-1600
stephen.brooks@nelsonmullins.com
lucas.westby@nelsonmullins.com

Daniel L. Ring (*pro hac vice*)
MAYER BROWN LLP
71 S. Wacker Drive
Chicago, IL 60606
dring@mayerbrown.com
Telephone: (312) 701-8520
Facsimile: (312) 706-8675

Andrew E. Tauber (*pro hac vice*)
MAYER BROWN LLP
1999 K Street, N.W.
Washington, D.C. 20006
atauber@mayerbrown.com
Telephone: (202) 263-3324
Facsimile: (202) 263-5324

Attorneys for Defendants St. Jude Medical, S.C., Inc., et al.

ORAL ARGUMENT REQUESTED

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It is apparent on the face of the complaint that Plaintiff's claims fail as a matter of federal and state law and must therefore be dismissed.

Plaintiff alleges that her husband, Milton Sharp, suffered from cardiac arrhythmia. To treat his condition, Mr. Sharp received an implantable cardioverter defibrillator ("ICD") in 2004 and a Riata lead, an insulated wire which delivers signals that allow an ICD to detect an abnormal cardiac rhythm and deliver a shock to help the heart return to an appropriate rhythm. In 2011, Mr. Sharp's original ICD was replaced with a Fortify ICD, which was connected to the Riata lead, which remained in place. Plaintiff alleges that in 2015, over a decade after his Riata lead was implanted and four years after his ICD was replaced, Mr. Sharp suffered cardiac arrest and died.

As innovative Class III medical devices, the Riata lead and Fortify ICD were approved by the Food and Drug Administration ("FDA") through the agency's Premarket Approval ("PMA") process, which subjects devices to the highest level of scrutiny in the federal regulatory regime. Pursuant to that process, the FDA approved the design, manufacturing method, and labeling of the Riata lead and the Fortify ICD.

Claims arising from medical devices with premarket approval, like the devices at issue here, are limited by two federal statutes. Under 21 U.S.C. § 360k(a), as interpreted in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is

different from, or in addition to, any requirement applicable … to the device" under federal law. And under 21 U.S.C. § 337(a), as interpreted in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), private lawsuits that seek to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") are impliedly preempted.

Although lengthy, the Second Amended Complaint ("SAC" or "Complaint") fails to do what it must to state a claim that survives express preemption: plead facts plausibly suggesting that Defendants (collectively, "St. Jude") violated a federal requirement in a way that both caused Mr. Sharp's death and gives rise to liability under Georgia state law. Because Plaintiff admits that the devices at issue received premarket approval from the FDA, and because her manufacturing-defect claims rely on the supposed violation of purported federal requirements that do not exist and are not plausibly alleged, it is apparent on the face of the Complaint that her manufacturing-defect claims are preempted.

Similarly, it is apparent on the face of the Complaint that Plaintiff's failure-to-warn claims are preempted because they rest on St. Jude's alleged failure to report adverse events to the FDA, a theory the Eleventh Circuit has held is impliedly preempted by § 337(a). And because Plaintiff's negligence *per se* claim also attempts to enforce duties owed to the FDA, it too is impliedly preempted.

Even if Plaintiff's claims survived preemption, they fail on various state law

grounds. Thus, the Second Amended Complaint must be dismissed in its entirety.

BACKGROUND

A. Statutory And Regulatory Background.

When Congress enacted the Medical Device Amendments ("MDA") to the FDCA in 1976, it granted the FDA authority to regulate medical devices and created a "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. As part of that regime, Congress incorporated an express preemption clause, which specifies that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable … to the device" under federal law. 21 U.S.C. § 360k(a)(1).

Different types of devices receive different levels of scrutiny from the FDA. Devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are deemed "Class III" devices (21 U.S.C. § 360c(a)(1)(C)(ii)) and "incur the FDA's strictest regulation." *Buckman*, 531 U.S. at 344. Innovative Class III devices must receive premarket approval ("PMA") from the FDA before they may be sold. "Premarket approval is a 'rigorous' process." *Riegel*, 552 U.S. at 317 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)). "The FDA spends an average of 1,200 hours reviewing each application" and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and

effectiveness.'" *Id.* at 318 (quoting 21 U.S.C. § 360e(d)). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319.

The FDA has exclusive authority to enforce the FDCA. Congress has specified that "all" actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

B. Premarket Approval Of The Riata Lead And Fortify ICD.

That the FDA granted premarket approval to the Riata leads and the Fortify ICD is admitted by Plaintiff (SAC ¶¶ 64–65) and judicially noticeable.[1] The Riata leads were approved by a PMA Supplement on March 11, 2002. SAC ¶ 76; Tauber Decl. ¶ 1. The Fortify ICD (model CD2231-40/40Q) was approved on May 7, 2010. Tauber Decl. ¶ 2. Although both were subject to recall (SAC ¶¶ 7–8), the FDA has taken no action to revoke either device's premarket approval.

C. Plaintiff's Allegations.

Plaintiff alleges that her husband, Milton Sharp, was implanted with a Riata

[1] This Court may take judicial notice of the FDA's grant of premarket approval because it is "not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Courts often take notice of such approvals. *See, e.g., Scianneaux v. St. Jude Med. S.C., Inc.*, 961 F. Supp. 2d 808, 812 (E.D. La. 2013).

lead and an ICD in 2004. SAC ¶ 35. According to Plaintiff, Mr. Sharp died in 2015 after the "ICD failed to administer an appropriate shock to his heart," allegedly because "friction between the external insulation on the Riata lead and the ICD exposed the wires inside the lead" and caused a "malfunction." *Id.* ¶ 10. Plaintiff asserts seven claims against St. Jude, including manufacturing defect, failure to warn, and negligence *per se* claims. *Id.* ¶¶ 188–267.

LEGAL STANDARD

A complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This requires well-pleaded factual allegations that "raise a right to relief above the speculative level." *Id.* at 555. The court "need not accept factual claims that are internally inconsistent; facts which run counter to facts of which the court can take judicial notice; conclusory allegations; unwarranted deductions; or mere legal conclusions asserted by a party." *Willis v. Arp*, 165 F. Supp. 3d 1357, 1359 (N.D. Ga. 2016).

The Eleventh Circuit has held that "the affirmative defense of federal preemption can be the basis of a Rule 12(b)(6) motion" when the facts alleged demonstrate that preemption applies. *Land v. CIGNA Healthcare of Fla.*, 339 F.3d 1286, 1289 n.2 (11th Cir. 2003), *vacated on other grounds*, 542 U.S. 933 (2004). Thus, "a complaint may be dismissed … when its own allegations indicate the existence of

an affirmative defense." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *on reh'g*, 764 F.2d 1400 (11th Cir. 1985) (*en banc*); *accord Jones v. Bock*, 549 U.S. 199, 215 (2007); 5B C. Wright & A. Miller, Federal Practice and Procedure § 1357 (3d ed. 2004). Accordingly, district courts routinely dismiss—and the Eleventh Circuit routinely affirms the dismissal of—complaints on preemption grounds. *See, e.g.*, *Spain v. Brown & Williamson Tobacco Corp.*, 363 F.3d 1183, 1197 (11th Cir. 2004) (affirming dismissal of failure-to-warn claims on preemption grounds); *Stout v. Med-Trans Corp.*, 313 F. Supp. 3d 1289 (N.D. Fla. 2018) (dismissing claims as preempted). Indeed, preempted claims "***must*** be dismissed." *Clark v. PNC Bank, N.A.*, 2014 WL 359932, at *5 n.15 (N.D. Ga. 2014) (emphasis added).

ARGUMENT

I. PLAINTIFF'S CLAIMS ARE PREEMPTED BY FEDERAL LAW.

As is evident on the face of the complaint, Plaintiff's claims are expressly and/or impliedly preempted. The MDA's preemption clause, 21 U.S.C. § 360k(a), prohibits the use of state law to enforce any requirement that is "different from, or in addition to" requirements imposed by the FDA. Section 360k(a) creates a two-step test: ***First***, a court must determine whether "the Federal Government has established requirements applicable to" the particular device. *Riegel*, 552 U.S. at 321. In *Riegel*, the Supreme Court held that "[p]remarket approval … imposes [federal]

'requirements'" as that term is used in § 360k(a). *Id.* at 322. Thus, "PMA-approved device[s]," like those at issue here, "automatically satisf[y] the first prong of the *Riegel* framework." *Thomas v. Alcon Labs.*, 116 F. Supp. 3d 1361, 1367 (N.D. Ga. 2013) (dismissing claims as preempted).

Second, the court must determine whether the claim would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements. *Riegel*, 522 U.S. at 322. There is a narrowly circumscribed exception to preemption under § 360k(a) for claims based on state-law duties that "'parallel,' rather than add to, federal requirements." *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495). To be "parallel," a claim must rest on the violation of a state-law requirement that is "identical" to an existing federal requirement. *Lohr*, 518 U.S. at 495; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) ("the plaintiff must show that the requirements are '*genuinely* equivalent'").

To survive express preemption, plaintiffs must "allege facts in their complaint demonstrating the presence of the elements of a parallel claim." *Wolicki-Gables*, 634 F.3d at 1302. In particular, "the parallel claims must be specifically stated in the initial pleadings and the plaintiff must allege that the defendant violated a particular federal specification concerning the device at issue." *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *5 (N.D. Ga. 2011). Moreover, "[t]o properly allege parallel claims, the

complaint must further set forth facts pointing to specific [pre-market approval] requirements that have been violated." *Id.*

A claim that avoids express preemption may still be impliedly preempted. In enacting the FDCA, Congress not only declined to create a private cause of action, but affirmatively required that any action to enforce the FDCA "be by and in the name of the United States" (21 U.S.C. § 337(a)), thereby mandating that the FDCA and its implementing regulations be "enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. Thus, "traditional state-law tort claims survive implied preemption" only "so long as they don't seek to privately enforce a duty owed to the FDA." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017).

Together, *Riegel* and *Buckman* "create[] what some federal courts have described as a 'narrow gap' for pleadings." *Mink*, 860 F.3d at 1327. "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Id.* Plaintiff's claims do not fit through that narrow gap and must therefore be dismissed.

A. Plaintiff's Manufacturing Defect Claims Are Preempted.

Plaintiff has failed to state a manufacturing-defect claim that escapes express preemption. Plaintiff does not allege facts plausibly suggesting that a PMA

requirement was violated, nor explain how any supposed violation caused Mr. Sharp's injuries.

1. Plaintiff's claim regarding the Riata leads is preempted.

Plaintiff relies on five purported PMA requirements, contending that St. Jude: (1) manufactured the Riata leads with "inconsistent insulation diameters" although "insulation diameters are," supposedly, "required by the PMA, and federal requirements to be consistent" (SAC ¶¶ 144, 205); (2) "inconsistently applied a lubricious interface between the inner and outer insulation in violation of the PMA" (*id.* ¶¶ 147, 208); (3) "failed to follow the approved methods of curing ... during the manufacture of the Leads" (*id.* ¶¶ 148, 209); (4) "failed to comply with the approved methods of … sterilization during the manufacture of the Leads" (*id.*); and (5) failed to apply "a controlled, uniform degree of force when applying the crimp" (*id.* ¶¶ 149, 210).

The purported federal requirements upon which Plaintiff bases her claims are inadequately alleged and do not exist. Four of the alleged requirements are made entirely of whole cloth. As found in *Pinsonneault v. St. Jude Medical, Inc.* after discovery, "there is no evidence … that the FDA required that the Riata leads be made with uniform insulation thickness," "no evidence of any requirement for a controlled, uniform degree of force when crimping," and "no evidence of any federal requirements as to curing or lubricious interface." 2014 WL 2879754, at *10 (D.

Minn. 2014). Plaintiff offers no well-pleaded allegations of fact to support the existence of any such requirements, and "the summary judgment decision in [*Pinsonneault*] drastically decreases the reasonableness of [her] expectation that discovery will reveal evidence proving [her] claims." *Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 231 (W.D.N.Y. 2016) (granting motion to dismiss on preemption and other grounds).

That leaves only Plaintiff's allegation that St. Jude "applied for and received approval for multiple changes to the ... sterilization process" but then violated the supposedly revised sterilization requirements in some unspecified way. SAC ¶ 148. The original Riata PMA required only that the leads be sterilized using a particular substance. Plaintiff does not allege that St. Jude failed to use that substance or otherwise violated the initial PMA. Rather, Plaintiff alleges in conclusory fashion that St. Jude violated unspecified "changes" purportedly approved via subsequent supplemental PMA applications. *Id*. That vague allegation falls short of what is necessary to adequately allege the existence of a federal requirement. As the Eleventh Circuit has held, Plaintiff must identify "specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301.

Plaintiff also asserts that St. Jude violated certain provisions of the FDA's Current Good Manufacturing Practices and Quality System Regulations. SAC ¶¶ 197–

99. But, as Judge Evans has explained, "[c]ourts have held that the regulations contained in the QSR portion of the Code[] cannot serve as the basis for a parallel claim" because of their "intentionally vague and open-ended nature." *Thomas*, 116 F. Supp. 3d at 1368 (quotation omitted). "[A]llowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits," which is "precisely the result that the MDA preemption provision seeks to prevent." *Id.* (quotation omitted); *Horn v. Bos. Sci. Neuromodulation Corp.*, 2011 WL 3893812, at *9 (S.D. Ga. 2011) ("any claim based on QSRs or similarly vague FDA regulations would fail").[2]

Even if a plaintiff could sometimes invoke such violations to support a parallel claim, she must allege "specific facts about when and how these violations occurred in the manufacture of the specific device at issue." *Cline v. Advanced Neuromodulation Sys., Inc.*, 921 F. Supp. 2d 1374, 1381 (N.D. Ga. 2012). Plaintiff has not done so here. Instead, she asserts that St. Jude violated the regulations in manufacturing the Riata

[2] To be clear, St. Jude is not arguing that these regulations cannot serve as a basis for a parallel claim because they are not device-specific. *Cf. Mink*, 860 F.3d at 1331 n.3. Rather, their deliberate vagueness and flexibility (allowing manufacturers great discretion subject to FDA oversight) means that permitting state-law claims predicated on their purported violation would necessarily impose state-law requirements "different from, or in addition to," the federal requirements. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009), *aff'd sub nom. Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

leads, without identifying ***how*** they did so, or how those violations affected the lead that Mr. Sharp received.

Regardless, Plaintiff's manufacturing-defect claim would be expressly preempted even if Plaintiff identified a pertinent federal violation. ***First***, any purported violations have been inadequately alleged. A plaintiff "cannot simply incant the magic words [Defendant] violated FDA regulations in order to avoid preemption." *Hawkins v. Medtronic, Inc.*, 2014 WL 346622, at *9 (E.D. Cal. 2014) (quotation omitted) (granting motion to dismiss on preemption grounds). Yet "incant the magic words" is all that Plaintiff does. Her Complaint contains no facts plausibly suggesting that St. Jude ever violated any of the purported requirements, let alone while manufacturing the particular lead Mr. Sharp received.[3] Lacking "specific factual support in [her] complaint identifying how St. Jude failed to comply with federal requirements in manufacturing [her husband's] device," the Complaint "fail[s] to state a plausible claim and must be dismissed." *Viserta v. St. Jude Med., Inc.*, 2012 WL 667814, at *4 (D.S.C. 2012) (granting motion to dismiss on preemption grounds).

[3] Indeed, the Complaint alleges facts that make the existence of any such violation *implausible*. According to the agency's recall notice—which the Complaint incorporates by reference (*cf.* SAC ¶¶ 155–56)—the "FDA[-d]etermined [c]ause" for the recall of the Riata leads was not manufacturing defects, let alone manufacturing defects caused by a deviation from the device's PMA manufacturing specifications, but "[d]evice [d]esign." Tauber Decl. Ex. 3.

Second, even if it did plausibly suggest a PMA violation, the Complaint fails to adequately allege that any such violation caused Mr. Sharp's death. With respect to sterilization, it alleges only that the purported "[f]ailure to follow the approved … sterilization processes resulted in reduced tensile strength of the silicone insulation." SAC ¶ 209. It alleges no facts that, if true, would establish a connection either (1) between a deviation from a sterilization requirement and reduced tensile strength of the lead's insulation; or (2) between reduced tensile strength and Mr. Sharp's death. The same is true of every PMA violation alleged by Plaintiff.

Tacitly acknowledging her failure to plead facts sufficient to plausibly allege causation, Plaintiff implicitly invokes the *res ipsa loquitur* doctrine, baldly asserting that "[t]he failure of the Device was apparently unrelated" to other factors, "suggesting that the manufacturing problems are responsible for the failure of the devices." SAC ¶ 212. But Plaintiff cannot rely on the *res ipsa loquitur* doctrine to satisfy her obligation to adequately plead causation.

Under Georgia law, the doctrine does not apply unless the accident at issue "is of a kind which ordinarily does not occur in the absence of someone's negligence" and was "caused by an agency or instrumentality within the exclusive control of the defendant." *Aderhold v. Lowe's Home Ctrs., Inc.*, 643 S.E.2d 811, 812–13 (Ga. Ct. App. 2007) (quotation omitted). Here, neither condition is satisfied. To start, the Riata

lead was implanted in Mr. Sharp in 2004 and had not been in St. Jude's "exclusive control" for 11 years when it allegedly malfunctioned in 2015. SAC ¶¶ 10, 35. Moreover, an alleged malfunction in a Class III medical device is not an event "which ordinarily does not occur in the absence of someone's negligence." The FDA "may … approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318. Thus, "one may not infer a defect in the product simply because a patient encountered negative side effects in using it." *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 531–32 (S.D. Tex. 2009), *aff'd*, 631 F.3d 777 (5th Cir. 2011). Rather, because the "safety and reliability" of implantable devices "cannot be guaranteed indefinitely in the 'extremely hostile environment of the human body'" (*Walker v. Medtronic, Inc.*, 670 F.3d 569, 580 (4th Cir. 2012)), invocation of "*[r]es ipsa loquitur* does not suffice" to overcome express preemption under § 360k(a). *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008).

2. Plaintiff's claim regarding the Fortify ICD is preempted.

As for the Fortify ICD and its purportedly defective battery, Plaintiff's allegations are irrelevant because she does not allege that any defect in the Fortify ICD battery caused Mr. Sharp's injuries. Rather, she alleges that the device's alleged failure to deliver a shock was caused by "friction between the external insulation ***on the Riata lead*** and the ICD." SAC ¶ 10 (emphasis added).

Regardless, the Second Amended Complaint does not even purport to identify a manufacturing defect in the Fortify ICD, let alone one caused by violation of a PMA requirement. Plaintiff claims that the Fortify ICD battery "susceptible to premature battery depletion." SAC ¶ 189. In particular, she alleges that the battery as designed "failed to include a necessary level of insulation to prevent rapid battery depletion" SAC ¶ 189. But Plaintiff identifies no PMA requirement—or other federal requirement—that St. Jude purportedly violated. The conclusory assertion that use of the battery without additional insulation was "in violation of the PMA" (*id.*) is not enough; Plaintiff must "set forth facts pointing to specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301.

Regardless, using such a battery would, at most, constitute an alleged *design* defect, not a *manufacturing* defect. Indeed, Plaintiff repeatedly alleges that the battery used in the Fortify ICD was itself defectively designed or rendered the Fortify ICD defectively designed. *See, e.g.*, SAC ¶ 181 (St. Jude "ma[de] a design change to address the defect"); *id.* ¶ 184 (battery depletion was "due to … defective design"). But *Riegel*—which held that § 360k(a) preempts "claims of strict liability … and negligence in the design" of a device (552 U.S. at 320)—squarely forecloses any such claim, which would necessarily "establish design requirements different from, or in addition to, federal requirements for the … device." *Caplinger v. Medtronic, Inc.*, 921

F. Supp. 2d 1206, 1222 (W.D. Okla. 2013) (dismissing claims on preemption grounds), *aff'd*, 784 F.3d 1335 (10th Cir. 2015) (Gorsuch, J.).[4]

B. Plaintiff's Failure-To-Warn Claims Are Preempted.

However construed, Plaintiff's failure-to-warn claims are also preempted.

1. Plaintiff's claim that St. Jude should have provided additional or different warnings is preempted.

To the extent Plaintiff claims that St. Jude had a "duty to provide ongoing warnings and instructions regarding safety hazards associated with the Leads" (SAC ¶ 223), her claim is expressly preempted. In granting premarket approval, the FDA approved the labeling for the Riata leads and the Fortify ICD. *See* 21 U.S.C. § 360e(c)(1)(F). Plaintiff does not allege that St. Jude failed to provide the lead's FDA-mandated labeling; rather, she alleges that St. Jude should have given unspecified additional "ongoing warnings and instructions." But, as the Supreme Court explained in *Riegel*, § 360k(a) "[s]urely … would preempt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings." 552 U.S. at 329. Thus, any claim that a device

[4] Moreover, as to both the Riata leads and the Fortify ICD, Plaintiff's "strict liability claim cannot survive preemption because Georgia's strict-liability provision does not require the violation of any standard of care, let alone a standard that parallels federal regulations," and therefore "cannot be genuinely equivalent to Defendant's requirements under federal law." *Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1281 (N.D. Ga. 2014).

manufacturer had an obligation to provide additional warnings would "impose different requirements under state law than those required under federal law," and is therefore preempted. *Leonard*, 2011 WL 3652311, at *8.[5]

2. Plaintiff's claim that St. Jude allegedly failed to report adverse events to the FDA is preempted.

Plaintiff also claims that St. Jude is liable for allegedly failing to report adverse events involving the Riata leads and Fortify ICD. If Plaintiff's theory is that St. Jude had a duty to provide such reports directly to patients and physicians (*see* SAC ¶ 226), the claim is expressly preempted because it "seeks to impose a duty to warn onto defendants that is broader and in addition to those required by federal law." *Martin v. Medtronic, Inc.*, 2017 WL 825410, at *7 (E.D. Cal. 2017); *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring) ("any attempt to predicate the … claim on an alleged state law duty to warn doctors directly would [be] expressly preempted").

If, instead, Plaintiff claims that St. Jude is liable for having allegedly failed to submit such reports to the FDA (*see* SAC ¶ 227), then her failure-to-warn claim is

[5] Plaintiff also alleges that St. Jude was obligated to "fil[e] a PMA supplement" (SAC ¶ 229) to "petition[] the FDA for a label change" (*id.* ¶ 234). But any duty to do so "exist[s] solely by virtue of the FDCA" and thus may be enforced only by "the Federal Government rather than private litigants." *Buckman*, 531 U.S. at 349 n.4, 353. Hence, any claim based on that alleged duty is preempted under *Buckman*. *See e.g.*, *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) (dismissing complaint on preemption grounds).

impliedly preempted under binding Eleventh Circuit precedent. In *Mink v. Smith & Nephew, Inc.*, the plaintiff alleged—like Plaintiff here—that the defendant "failed to adequately investigate adverse events and complaints and failed to properly report these issues to the FDA." 860 F.3d at 1330. "Because this theory of liability is based on a duty to file a report with the FDA," the court explained, "it is very much like the 'fraud-on-the FDA' claim the Supreme Court held was impliedly preempted in *Buckman*." *Id.* Thus, "federal law preempts" Plaintiff's claim "to the extent it [is] premised on a 'failure to report' theory." *Id.*[6]

Regardless, Plaintiff's allegations do not support her claim. The allegation that St. Jude failed to report known adverse events is simply an insufficient "'naked assertion[]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555, 557). In an attempt to salvage her claim, Plaintiff points to several FDA documents that supposedly found deficiencies in St. Jude's reporting practices. But even as alleged in the Complaint, none of those documents identified *any* adverse events that St. Jude failed to report to the FDA; instead, they purported to find that St. Jude submitted incomplete (SAC ¶ 108) or

[6] The claim is also expressly preempted because "the federal duty *to report certain information to the FDA* is not 'identical,' and thus not parallel, to the state-law duty *to provide warnings to patients or their physicians*." *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016) (quoting *Lohr*, 518 U.S. at 495).

untimely (*id.* ¶ 109) reports.

Moreover, Plaintiff does not adequately allege that St. Jude's alleged failure to report adverse events caused her husband's death. To sufficiently allege causation, she must plead facts that, if true, would show (among other things): that St. Jude knew of relevant adverse events that it did not report to the FDA; that had the events been reported, the agency would have made the reports public; that had the reports been made public, Mr. Sharp's physician would have seen them; and that, having seen the reports, the physician would have altered his conduct in a way that would have prevented Mr. Sharp's death. No such facts are alleged.

Far from pleading facts sufficient to establish the necessary causal nexus, Plaintiff alleges facts that *disprove* the existence of any such connection. To start, Plaintiff alleges that Mr. Sharp's lead was interrogated ***eight times*** between March 2012 and July 2015, and that ***each time*** the interrogation "revealed a patient safety alert" advising Mr. Sharp and his physician of "the recall of the Riata lead" occasioned by "premature erosion of the [lead's] insulation," and informing them of "[l]ead impedance greater than upper limit." SAC ¶¶ 40–46. Moreover, Plaintiff herself alleges that the purported risks of the Riata leads and the Fortify ICD were well-known long before Mr. Sharp's death, including through (1) ***3,689*** adverse-event reports as of 2009 (*id.* ¶ 106); (2) multiple FDA reports, including the very reports

Plaintiff uses to support her claims (*id.* ¶¶ 101–15, 124–42); (3) publicly available journal and newspaper articles (*id.* ¶¶ 119–21, 169–80); (4) two "Dear Doctor" letters about the Riata leads, the latter of which was subsequently classified as a Class I Recall (*id.* ¶¶ 155–68); and (5) a Class I Recall of the Fortify ICD (*id.* ¶ 182). Despite all this information, Mr. Sharp's physician did not recommend extraction of Mr. Sharp's lead. Consequently, there is no reason to credit Plaintiff's conclusory assertion that additional information from a handful of supposedly unreported adverse events would have affected the physician's treatment decisions and resulting in removal of the lead before any alleged failure. The court's "duty to accept the facts in the complaint as true does not require [it] to ignore specific factual details of the pleading in favor of general or conclusory allegations." *Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1205–06 (11th Cir. 2007).

C. Plaintiff's Negligence-*Per-Se* Claim Is Preempted.

Finally, Plaintiff's negligence-*per-se* claim is impliedly preempted. Claims premised on "a violation of the FDCA" are impliedly preempted "because the FDA has the exclusive power to enforce the FDCA" and there is therefore "no private right to enforce the statute." *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 936 (6th Cir. 2014). A negligence-*per-se* claim, by definition, depends on the alleged violation of a statutory or regulatory provision. Here, Plaintiff's claim

rests on St. Jude's purported violation of the FDCA and its implementing regulations. *See* SAC ¶ 254. Thus, "'the existence of these federal enactments is a critical element in [her] case.'" *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) (quoting *Buckman*, 531 U.S. at 353) (affirming dismissal on preemption grounds).

Indeed, the Eleventh Circuit's decision in *Mink* disposes of Plaintiff's negligence-*per-se* claim. *Mink* held that claims based on duties "owed to the FDA" are impliedly preempted. 860 F.3d at 1330. "*Mink* therefore instructs that implied preemption prohibits state law claims that seek to privately enforce duties owed to the FDA pursuant to the FDCA." *Markland v. Insys Therapeutics, Inc.*, 2017 WL 4102300, at *8 (M.D. Fla. 2017) (dismissing claim on preemption grounds). While Plaintiff "couches [her] claim in the language of negligence," she ultimately uses St. Jude's alleged "violation of federal law to substantiate the existence of a state tort claim." *Id.* at *10. "This [s]he cannot do." *Id.* In short, Plaintiff's negligence-*per-se* claim is impliedly preempted because Plaintiff "cannot create a private right of action under the guise of a state law claim." *Leonard*, 2011 WL 3652311, at *8.

II. PLAINTIFF'S CLAIMS FAIL UNDER STATE LAW.

Even if Plaintiff's claims survived preemption, they fail under state law.

A. The Manufacturing-Defect Claims Are Inadequately Pleaded.

To state a manufacturing defect claim under Georgia law, the Plaintiff must

identify "a defect in the product" and a causal link between the "manufacturing defect and [her] injury." *Boswell v. OHD Corp.*, 664 S.E.2d 262, 263 (Ga. Ct. App. 2008). Plaintiff fails to adequately plead either element.

Although the SAC asserts that Riata leads *in general* were prone to unspecified manufacturing defects, it alleges no facts to plausibly suggest that *Mr. Sharp's lead in particular* suffered from any such defect. Indeed, its allegations undermine Plaintiff's claim that Mr. Sharp's lead suffered from a manufacturing defect. She alleges that as of November 2011 the "published failure rates for the Riata Leads … increased to 0.63%." SAC ¶ 161. Thus, even if one (unrealistically) assumes that every lead that failed had failed because of a manufacturing defect, less than 1% of Riata leads suffered from a manufacturing defect according to Plaintiff's own allegations. Moreover, as explained above (at 13–14), that the lead allegedly malfunctioned—after functioning for over a *decade* (SAC ¶¶ 35–36, 49, 51)—does not mean that it suffered from a defect, let alone a manufacturing defect.

Similarly, while Plaintiff claims that the batteries in the Fortify ICDs "were susceptible to premature battery depletion" (SAC ¶ 189), she does not allege that the battery in Mr. Sharp's Fortify ICD suffered from premature depletion. Indeed, she alleges that the defect, if any there was, was present in Mr. Sharp's Riata lead. *See supra* at 14–16.

Moreover, although the SAC conclusorily alleges that a purported manufacturing defect "caused Mr. Sharp's death" (SAC ¶ 213), it alleges no facts to support that assertion. As the Supreme Court held in *Twombly* and *Iqbal*, Plaintiff's "unadorned, the-defendant-unlawfully-harmed-me accusation" is insufficient to survive a motion to dismiss. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Absent facts plausibly suggesting that "the particular [lead] that was implanted in [Mr. Sharp] was defective" and as a result failed in a manner that caused his death, the Complaint does "not come close to alleging facts sufficient to 'raise a right to relief above the speculative level.'" *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 789 (D. Minn. 2009) (quoting *Twombly*, 550 U.S. at 555) (dismissing claims on preemption grounds).

B. Plaintiff's Failure-To-Warn Claims Fail.

Plaintiff's failure-to-warn claims fail because Georgia has adopted the learned-intermediary and sophisticated-user doctrines. Under the learned intermediary doctrine, "the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003). But under the sophisticated user doctrine, there is no duty to warn "one in a particular trade or profession against a danger generally known to that trade or profession." *Powell Duffryn Terminals, Inc. v. Calgon Carbon Corp.*, 4 F. Supp. 2d

1198, 1203 (S.D. Ga. 1998) (quotation omitted).

The purported risks of the Riata leads were known to the medical community long before Mr. Sharp's death through the FDA approved labeling, which is conclusively adequate as a matter of law. Moroever, as explained above, according to Plaintiff herself, those risks were also disclosed through the thousands of adverse events reported on the FDA's MAUDE database, and in multiple FDA publications and journal articles. *See supra* at 19–20. Moreover, Mr. Sharp's physician interrogated his Riata leads multiple times and discovered that they were subject to a recall. *Id.* Regardless, Plaintiff's failure-to-warn claims are inadequately pleaded. Plaintiff identifies no relevant adverse events that St. Jude knew of but failed to report, nor does she plausibly allege how the reporting of those unidentified events would have prevented Mr. Sharp's death. *See supra* at 16–20.

C. Plaintiff's Negligence-*Per-Se* Claim Fails.

It "is well settled that violating statutes and regulations does not automatically give rise to a civil cause of action" under Georgia law. *Govea v. City of Norcross*, 608 S.E.2d 677, 683 (Ga. Ct. App. 2004). Rather, Plaintiff must show that the legislature intended "to create a civil cause of action for damages by an alleged victim." *Id.* But § 337(a)—"sometimes called the 'no-private-right-of-action' clause" (*Mink*, 860 F.3d at 1327)—declares that "***all***" actions to enforce the FDCA "shall be by and in the

name of the United States." 21 U.S.C. § 337(a) (emphasis added). Thus, "Plaintiff cannot assert a negligence *per se* claim based on violations of the FDCA or the FDA's implementing regulations." *McClelland v. Medtronic, Inc.*, 2012 WL 5077401, at *5 (M.D. Fla. 2012) (dismissing claims on preemption grounds).

Moreover, Plaintiff's negligence-*per-se* claim also fails to satisfy Rule 8(a). Although the Complaint lists a bevy of federal regulations to which St. Jude was purportedly subject (SAC ¶ 254), it fails to specify *which* regulations St. Jude is alleged to have violated and *how* it supposedly violated them with respect to Mr. Sharp's lead. As a result, St. Jude is forced "to speculate as to which provisions Plaintiff is suing under" and as to "how" it purportedly "violated such provisions," thereby depriving St. Jude of "fair notice of the claim asserted and the grounds upon which it rests." *Anderson v. Cent. Pac. HomeLoans, Inc.*, 2011 WL 3439939, at *4 (D. Haw. 2011). Moreover, the Second Amended Complaint alleges no facts plausibly suggesting that St. Jude violated *any* of the regulations listed, much less facts plausibly suggesting that a violation caused Plaintiff's alleged injury.

CONCLUSION

Plaintiff's Second Amended Complaint should be dismissed.[7]

[7] Claims for loss of consortium and punitive damages are purely derivative. *Haynes v. Cyberonics, Inc.*, 2011 WL 3903238, at *9 (N.D. Ga. 2011). Because Plaintiff's other claims fail, these claims must be dismissed as well.

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Respectfully submitted,

/s/ Lucas A. Westby
Stephen M. Brooks
Georgia Bar No. 085151
Lucas A. Westby
Georgia Bar No. 594008
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Telephone: (404) 322-6000
Facsimile: (404) 322-1600
stephen.brooks@nelsonmullins.com
lucas.westby@nelsonmullins.com

Daniel L. Ring (*pro hac vice*)
MAYER BROWN LLP
71 S. Wacker Drive
Chicago, IL 60606
dring@mayerbrown.com
Telephone: (312) 701-8520
Facsimile: (312) 706-8675
dring@mayerbrown.com

Andrew E. Tauber (*pro hac* to be filed)
MAYER BROWN LLP
1999 K Street, N.W.
Washington, D.C. 20006
atauber@mayerbrown.com
Telephone: (202) 263-3324
Facsimile: (202) 263-5324
atauber@mayerbrown.com

Attorneys for Defendants St. Jude Medical, S.C., Inc., et al.

LR 5.1(B) CERTIFICATE OF COMPLIANCE

The undersigned certifies, pursuant to Local Rules 5.1(B) and 7.1(D), that the foregoing has been prepared in size 14 Times New Roman.

/s/ Lucas A. Westby
Lucas A. Westby

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing has been filed on October 9, 2018 using the Court's CM/ECF system, which will send notice of electronic filing to all parties registered with the system.

/s/ Lucas A. Westby
Lucas A. Westby